DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

April 6, 2015

Concentric Medical, Inc.
Mr. Bill Hyatt
Regulatory Affairs Manager
301 East Evelyn Avenue
Mountain View, California 94041

Re: K143077
Trade/Device Name: Trevo XP ProVue Retriever (6x25 mm)
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: NRY
Dated: March 3, 2015
Received: March 6, 2015

Dear Mr. Hyatt:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Carlos L. Pena -S

Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143077

Device Name
Trevo XP ProVue Retriever (6x25 mm)

Indications for Use *(Describe)*
The Trevo XP ProVue Retriever (6x25 mm) is intended to restore blood flow in the neurovasculature by removing thrombus in patients experiencing ischemic stroke within 8 hours of symptom onset. Patients who are ineligible for intravenous tissue plasminogen activator (IV t-PA) or who fail IV t-PA therapy are candidates for treatment.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

Trade Name:	Trevo XP ProVue Retriever (6x25 mm)
Common Name:	Catheter, Thrombus Retriever
Classification Name:	Percutaneous Catheter, 21CFR 870.1250 Class II
Product Code:	**NRY**
Submitter:	**Concentric Medical, Inc.** 301 E. Evelyn Avenue Mountain View, CA 94041 Tel 510-413-2148 Fax 510-413-2558 Facility Registration #2954917
Contact:	**Bill Hyatt** Manager, Regulatory Affairs
Date Prepared:	**April 2, 2015**
Predicate Device:	**Trevo XP ProVue Retriever (4x20mm) (K132641)**

Device Description

The Trevo XP ProVue Retriever (6x25mm) consists of a flexible, tapered core wire with a shaped section at the distal end. It is designed to restore blood flow in the neurovasculature by removing thrombus in patients experiencing ischemic stroke. Radiopaque platinum wires in the shaped section and radiopaque markers on the distal end allow fluoroscopic visualization. Retriever dimensions are indicated on the product label. The Retriever has a hydrophilic coating to reduce friction during use. A torque device and an insertion tool are provided with the Retriever. The proximal end of the device is compatible with the Abbott guide wire extension to facilitate removal or exchange of a catheter while maintaining the Retriever position in the vessel.

Indications for Use

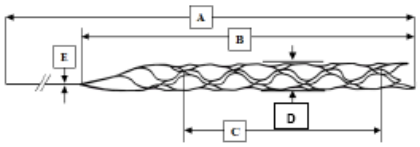
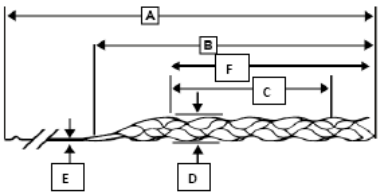
The Trevo XP ProVue Retriever (6x25mm) is intended to restore blood flow in the neurovasculature by removing thrombus in patients experiencing ischemic stroke within 8 hours of symptom onset. Patients who are ineligible for intravenous tissue plasminogen activator (IV t-PA) or who fail IV t-PA therapy are candidates for treatment.

Technological Characteristics and Product Feature Comparison

The Trevo XP ProVue Retriever (6x25mm) is substantially equivalent to the primary predicate device in terms of basic design, materials used, and function. A comparison of the subject device with Primary Predicate Trevo XP ProVue Retriever (4x20mm) is summarized in the below table.

Product Feature Comparison of Subject Device with Primary Predicate Device Trevo XP ProVue Retriever (4x20mm) (K132641)

Feature	**Primary Predicate** **Cleared Trevo XP ProVue Retriever (4x20mm) (K132641)**	**Subject Device** **Trevo XP ProVue Retriever (6x25mm)**
Indications for Use	The Trevo XP ProVue Retriever is intended to restore blood flow in the neurovasculature by removing thrombus in patients experiencing ischemic stroke within 8 hours of symptom onset. Patients who are ineligible for intravenous tissue plasminogen activator (IV t-PA) or who fail IV t-PA therapy are candidates for treatment.	Same as K132641
Device Description	The Retriever consists of a flexible, tapered core wire with a shaped section at the distal end. Platinum markers at the distal end allow fluoroscopic visualization. In addition, the shaped section is also radiopaque. Retriever dimensions are indicated on product label. The Retriever has a hydrophilic coating to reduce friction during use. The Retriever has a shaft marker to indicate proximity of Retriever tip relative to Microcatheter tip. A torque device is provided with the Retriever to facilitate manipulation. An insertion tool is provided to introduce the Retriever into a Trevo® Microcatheter.	Same as K132641 with the exception that the subject Retriever is introduced via an XT-27 Microcatheter (whereas the predicate device is introudced via a Trevo® Microcatheter)
Target Population	Patients with symptoms of an ischemic stroke	Same as K132641
Anatomical Sites	Neurovasculature	Same as K132641

Feature	**Primary Predicate** **Cleared Trevo XP ProVue Retriever (4x20mm) (K132641)**	**Subject Device** **Trevo XP ProVue Retriever (6x25mm)**
Accessory Devices Provided (not in direct contact with patient)	Insertion tool and torque device provided in product package	Same as K132641
Microcatheter Compatibility	Trevo Pro 18 Microcatheter	Excelsior XT-27 Microcatheter
Materials	Core Wire Material: Nitinol (nickel titanium alloy) Distal Shaped Section Material: Nitinol Coil Material Distal to Distal Shaped Section : Platinum/Tungsten Shaped Section Radiopaque Wire: Platinum/Tungsten Coil Material Proximal to Shaped Section: 304 Stainless Steel Solder: Gold/Tin Hydrophilic Coating: Sodium hyaluronate mixture	Same as K132641
Dimensional Drawing		
Overall Length (A)	180cm	180cm
Total Shaped Section Length (nominal) (B)	32mm	40mm
Active Shaped Section Length (nominal) (C)	20mm	25mm
Shaped Section Diameter (nominal) (D)	4mm	6mm

Feature	**Primary Predicate** **Cleared Trevo XP ProVue Retriever (4x20mm) (K132641)**	**Subject Device** **Trevo XP ProVue Retriever (6x25mm)**
Proximal Core Wire Diameter (E)	0.0180in	Same as K132641
Length of the non-tapered portion of shaped section (F)	Not provided in labeling	30mm
Shaped section	4 rows and 4 rings of cells.	5 rows and 5 rings of cells.
Hydrophilic coating length	Coating extends from the proximal end of the core wire up to the proximal coil.	Coating extends from a point 80cm distal to the proximal end of the core wire up to the proximal coil to enable physician to hold the device more securely.
Shaped section distal platinum coil markers	Platinum markers attached to 3 distal tips of the distal end of the shaped section.	Platinum markers attached to 3 distal tips of the distal end of the shaped section.
Radiopaque platinum wire woven into shaped section	Three platinum wires woven on shaped section struts.	Four platinum wires woven on shaped section struts.
Core wire marker band placement and presence	Core wire marker bands at 59.53” from the proximal end of the shaped section.	Core wire marker bands at 57.56” from the proximal end of the shaped section. (~5cm more distal) to allow compatibility with the XT-27 Microcatheter.
	6 marker bands are present on the core wire.	4 marker bands are present on the core wire.
Packaging Materials and Configuration	Polyethylene Hoop, polycarbonate mounting card, Tyvek/Film Pouch, HDPE Tubing Clips, Chipboard carton	Same as K132641
Sterilization Method	100% EtO	Same as K132641
How Supplied	Sterile/Single Use	Same as K132641

Risk Assessment

Risk assessment of the modifications has been conducted in accordance with EN ISO 14971:2012. Concentric Medical, Inc. has determined the modifications to the predicate device raise no new questions of safety or effectiveness. Results of verification and validation testing are appropriate for use in determining that the Trevo XP ProVue Retriever (6x25mm) is substantially equivalent to the predicate device.

The modifications did not result in the identification of any new failure modes nor were there any changes to existing failure modes, including no change to severity or occurrence; and, therefore, no change to overall residual risk.

Testing Summary

The results of verification and validation testing conducted on the Trevo XP ProVue Retriever (6x25mm) demonstrate that it performs as designed, and is suitable for its intended use. The verification and validation test results demonstrate that the Trevo XP ProVue Retriever (6x25mm) is substantially equivalent to the predicate device. Specifically, the following tests were performed on the proposed device:

	Test	Test Method Summary	Conclusions
1.	Dimensional Verification	Verified dimensions using specified measurement tool.	Dimensional verification meets acceptance criteria.
2.	Retriever Mid Joint Tensile Strength	Identified joint and cut sample for test. Recorded peak tensile force results.	Retriever Mid Joint Tensile Strength meets acceptance criteria.
3.	Retriever Tip Tensile Strength	Loaded sample. Recorded peak tensile force results.	Retriever Tip Tensile Strength meets acceptance criteria.
4.	Retriever Shaped Section Radial Force	Constrained and released shaped section of retriever to specified diameter. Recorded radial force results.	Retriever Shaped Section Radial Force meets acceptance criteria.
5.	Retriever/Vessel Interaction (Tip Flexibility)	Loaded sample so that the distal tip was flexed. Recorded peak compression/flex force results.	Retriever/Vessel Interaction (Tip Flexibility) meets acceptance criteria.
6.	Retriever Torque Tensile Durability	Gripped device and applied rotations to torque device. Pulled tensile cycles to a max load then last cycle to failure. Recorded results.	Retriever Torque Tensile Durability meets acceptance criteria.

	Test	Test Method Summary	Conclusions
7.	Retriever Platinum Wire Joint Strength	Identified joint and cut sample for test. Recorded peak tensile force results for each individual platinum wire.	Retriever Platinum Wire Joint Strength meets acceptance criteria.
8.	Retriever Platinum Wire and Joint Durability	Wrapped and unwrapped the entire length of the shaped section of the retriever (sheathed in insertion tool) around a pin and repeat. Performed visual inspection and recorded results. Performed deploy/reload cycles into insertion tool. Performed visual inspection and recorded results.	Retriever Platinum Wire and Joint Durability meet acceptance criteria.
9.	Radiopacity	Radiopacity was assessed based on visual assessment of the device being used under fluoroscopy.	Radiopacity meets acceptance criteria.
10.	Retriever / Microcatheter Deliverability	Measured the force to push the device through a tortuous model.	Retriever/Microcatheter Deliverability meets acceptance criteria.
11.	Particulate Evaluation	Measured total number of particulate and size of particulate generated during the simulated delivery, deployment and resheathing of the device. Particulate counting was assessed for ≥10µm, ≥25µm, and ≥50µm size ranges	All samples meet acceptance criteria.

	Test	Test Method Summary	Conclusions
12.	Coating Integrity Evaluation	A visual assessment of the coating integrity of the subject device was performed before (baseline) and after tracking through a tortuous path fixture representative of clinical conditions (simulated use). The visual assessment evaluation included a comparison of the visual assessment using higher magnification and a dye to assess the adhesion of the coating. Proximal and distal coating edges were evaluated to determine if the coating was intact. The entire coating length of the device was evaluated for defects (visible voids or scratches).	Neither the Baseline test articles nor the Post-tracking test articles exhibited any delamination at coating edges (either proximal or distal). The Baseline test articles did not exhibit any coating defects (voids or scratches). The Post tracking devices exhibited minimal defects along the 75cm coating length. When considered in conjunction with coating lubricity and durability results and the particulate generation results, the coating functions as intended and has exhibited appropriate integrity (via visual assessment) post simulated use.

	Test	Test Method Summary	Conclusions
13.	Simulated Use	Simulated use testing used a silicone neurovascular model cast from actual human neurovascular arteries. This bench testing model replicates the tortuosity, diameter and location of the arteries in the neurovasculature including the internal carotid artery (ICA) siphon. The model ends at the mid carotid arteries and proximal support is provided by a guide catheter. The model incorporates a re-circulating water bath at 37ºC pressurized between 2 – 2.5 psi (100 – 126 mm Hg) to simulate the human arterial circulation. All testing follows the procedural instructions outlined in the Instructions for Use. Simulated thrombus is used to assess the devices ability to retrieve clot.	Simulated Use meets acceptance criteria.

	Test	Test Method Summary	Conclusions
14.	Animal studies (acute and chronic)	Animal studies consisting of an acute animal (swine) study and a chronic animal (swine) study were performed using devices representative of the Trevo XP ProVue Retriever (6x25mm) and were conducted in compliance with applicable requirements in the GLP regulation (21 CFR Part 58). In both the acute and the chromic animal studies: • 12 test articles (4 per animal) were deployed • 6 test article treatment runs were conducted successfully in both internal maxillary arteries (IMAs) of animals which resulted in the assessment of 6 arteries (2 per animal). Safety (vessel response) was assessed based on the presence or absence of arterial transmural dissection or perforation due to Stentriever use in the treated vessels. Device/vessel interaction is considered acceptable (pass) if there is no evidence of arterial transmural dissection or perforation due to Stentriever use in the treated vessels based on results of angiography and histopathology.	<u>Acute Animal Study Results</u>: - Histopathology was consistent with arterial healing after routine catheterization commonly seen with guidewires / catheters. Angiography revealed No evidence of vessel dissection or perforation or thrombosis. <u>Chronic Animal Study Results</u>: - Histopathology was consistent with arterial healing after routine catheterization commonly seen with guidewires / catheters No evidence of vessel dissection or perforation Angiography revealed no evidence of vessel dissection or perforation at Day 0, and no angiographic evidence of stenosis, vessel irregularity, intimal flap or pseudoaneurysm was observed at treatment sites at Day 30 <u>Conclusion</u>: Animal studies meet acceptance criteria and are comparable to predicate device performance.

Biocompatibility

The Trevo XP ProVue Retriever (6x25mm) was assessed for impact to biocompatibility. Materials used in the Trevo XP ProVue Retriever (6x25mm) are all the same materials used in the cleared Trevo ProVue Retriever (K132641). Both the Trevo XP ProVue Retriever (6x25mm) and the cleared Trevo ProVue Retriever meet biological safety requirements per ISO 10993-1 for externally communicating medical devices with circulating blood contact for less than 24 hours.

Summary of Substantial Equivalence

The Trevo XP ProVue Retriever (6x25mm) is substantially equivalent to the predicate device with regard to device design, materials, intended use, and patient population. The conclusions drawn from risk assessments and the verification and validation testing conducted using the Trevo XP ProVue Retriever (6x25mm) demonstrate that the device performs as designed, is suitable for its intended use and is substantially equivalent to the legally marketed predicate device.